ALMAC

Partnering to Advance Human Health

Brochure

# Pharma Services

Tailor-made product development and commercial solutions.

**Advancing treatment together**

# About Almac Group

## The Almac Group is a global leader in providing a range of expert services and support across the drug development lifecycle.

A privately owned organisation, under the McClay Foundation, Almac has grown organically over the past five decades, now employing over 7,900 highly skilled individuals across 18 locations in Europe, the US and Asia.

Almac Group is comprised of 5 Business Units:

- Almac Diagnostic Services
- Almac Sciences
- Almac Pharma Services
- Almac Clinical Services
- Almac Clinical Technologies

Each Business Unit offers specialist and dedicated solutions at each phase of the product lifecycle providing the ability to select single or multiple, integrated solutions to meet your unique needs.

Our unique combination of inspirational people, exceptional innovation and outstanding quality, enables us to provide tailored solutions for your specific requirements - either on a single, standalone project or on a long-term basis as your strategic partner.


*Almac Group's range of innovative, integrated solutions*

>7,900
employees globally

18
locations

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Find out more about Almac Group

# About Almac Pharma Services

## With over 58 years' experience, Almac Pharma Services is an established, reliable and world leading outsourcing partner to the global pharmaceutical and biotechnology industry.

Employing over 2,000 highly skilled individuals across 4 locations in Europe and the US, we provide a range of tailored, quality-led and timely solutions from early and late phase pharmaceutical development, clinical and commercial drug product manufacture, product launch through to commercial packaging and global distribution.

Currently supporting client portfolios across more than 70 countries, our fully integrated, end-to-end solutions are tailored to meet the needs of your unique products, and, ultimately, your patients.


*Almac Pharma Services' range of innovative, integrated solutions*

>2,000
employees globally

>58
years experience

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Find out more about Almac Pharma Services

# Pharmaceutical Development solutions


Spanning both early and late phase development, our teams of expert scientists possess a wealth of experience in developing clinical candidates into optimal formulations and manufacturing high-quality oral dose products for all phases of clinical trials.

Operating both non-GMP and GMP facilities we have complementary equipment trains and integrated technical teams to facilitate technology transfer providing a seamless transition between formulation and process development, and clinical trial material manufacturing.

Through a range of flexible and fully tailored unit operations including blending, roller compaction, high shear granulation, encapsulation (including Xcelodose) micro encapsulation and fluid bed processing, we offer the following oral dose formulations with batch sizes ranging from grams to tons:

- API / powder in hard gelatin capsules or bottles, including micro-dosing
- Formulated blends in hard gelatin capsules or bottles
- Tablets (coated)
- Mini-tablets
- Granules
- Beads/pellets
- Non-sterile liquid in capsules or bottles
- Immediate and modified release
- Fixed dose combination products
- Potent and highly potent products (OEL as low as 0.05 µg/m³/8 hours)
- Specialist paediatric drug development expertise

*We offer vast technical experience, world class, dedicated project management, and a track record of on-time delivery.*

>110
live dev projects p.a.

>10
paediatric products developed p.a.

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Find out more about Pharmaceutical Development solutions


Clean Air
3000
Grant

# Analytical solutions


We employ over 700 highly skilled analysts working in state-of-the-art, fully certified GMP laboratories across Europe and the US with significant experience in the analysis of both small and large molecules.

We support drug substance (API) and drug product (finished product) analytics across all phases of clinical development through to commercial release. We offer a range of tailored services including:

- Method development
- Method validation
- Method transfer
- Stability programmes
- Release analysis: all lifecycle stages
- Spectroscopy services
- Investigational analysis
- Reference standard management
- Microbiological testing
- Physical sciences
- Bio-pharmaceutical testing
- Analytical support for clinical trial supplies

Supporting a range of test articles including:

- Raw materials
- Drug substance / API
- Drug product
- Medical devices
- Over encapsulated drug
- Small molecule
- Conjugates
- Peptides
- Biologics
- Clinical samples
- Highly potent
- Controlled substances

*Our in-depth technical expertise, combined with a wide range of advanced analytical instrumentation, delivers fast and reliable results.*

>1,000
analytical methods developed p.a.

>250
methods validated p.a.

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Find out more about Analytical solutions

# Commercial Manufacture solutions


Scaling up from our oral dose development assets and expertise through registration and launch into commercial supply, or transferring existing commercial products, we support your commercial manufacturing needs with flexibility and expertise.

With blend sizes from 10kgs up to 2.5 tons, our range of state-of-the-art processing equipment is designed to enable scalability to the batch size requirements of your product for a range of presentations including:

- Tablets
- Mini-tablets
- Capsules
- Powders
- Granules
- Beads/pellets
- Non-sterile liquids
- Potent and highly potent products (OEL as low as 0.05 µg/m³/8 hours)
- Specialist paediatric drug manufacturing expertise

*Our highly skilled scientists, technicians, project managers, and operators are equipped with the technical knowledge and experience to tackle the challenges associated with commercial manufacture.*

>20
live commercial manufacturing products p.a.

>30
therapeutic areas supported

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Find out more about Commercial manufacture solutions


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# Commercial Packaging solutions


Our high and low throughput operations provide the flexibility and efficiency necessary to meet your ongoing and fluctuating demand. Our commercial facilities in Europe and the US, combined with our local expertise offers flexible, quality-led commercial pharmaceutical packaging solutions tailored to meet your specific needs.

Our range of primary packaging solutions include:

- Tablets
- Mini-tablets
- Capsules
- Powders
- Granules
- Non-sterile liquid

Our secondary packaging, labelling and assembly capabilities include:

- Bottles
- Vials / ampoules
- Pre-filled syringes
- Wallets / blister cards
- Auto-injectors
- Cartons
- Sachets
- Stick packs
- Offline blister printing

Innovative, specialist packaging solutions including:

- Specialist paediatric drug packaging expertise
- Expert cell and gene therapy (ATMP) Ultra Low Temperature (ULT) solutions (-20$^0$ to -80$^0$)
- Complex medical kit assembly solutions via our unique, custom built semi-automated packaging technology

*Our experienced teams possess a wealth of technical knowledge and multi-market expertise to support your product launch (including rapid launch), and ongoing commercial packaging and distribution needs.*

>75
product / territory launches p.a.

>85
commercial products supported p.a.

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Find out more about Commercial Packaging solutions


ALMAC
ALMAC
ALMAC
PRODUCT NAME / ITEM CODE
LOT / BATCH

# Support solutions


We provide a wide range of tailored support and consultancy services to help guide you through every aspect of your unique development and commercialisation journey:

### World Class Project Management

Our dedicated, expert global project management teams possess many years of experience and act as an extension to your team to help navigate you through the complex landscape of drug development and commercialisation. This ensures your project is executed in the most efficient and effective way ensuring clear and constant communication throughout.

### Global Quality Management System

Operating under one global Quality Management System (QMS), we provide consistency, operational efficiency and standardisation across all our facilities ensuring clients receive the highest quality and streamlined service.

### Qualified Person (QP) Release Expertise

Our team of Qualified Persons (QPs) provide a range of services including release / import testing and QP certification and provide support to help navigate clients through the complex regulatory landscape, ensuring that all processes meet the latest regulatory guidance and expectations.

### Packaging and Artwork Design

With access to the most up-to-date design technology and software, our specialist in-house packaging and design team offers a full suite of design services to meet your requirements thereby streamlining the approval process, saving you time and money whilst ensuring your regulatory submission deadlines are met.

### Project Engineering Support

Our expert in-house engineering team offers innovative, bespoke design and construction of machinery and tooling to enhance efficiency across all our operations in addition to providing comprehensive maintenance services. Our Process Engineers optimise our manufacturing processes, ensuring they are both efficient and cost-effective.

### GMP Storage & Inventory Solutions

To meet your ongoing storage and inventory requirements, our dedicated, skilled logistics team manages multiple, modular GMP warehousing and storage capabilities for raw material, in-process supplies and finished product ranging from -80°C to +20°C. In addition, our Drug Enforcement Administration (DEA) and UK Home Office accreditation allows us to store schedule II-V controlled substances.

### Global Distribution

Our fully trained distribution team has a wealth of experience across global markets and provides tailored solutions to guarantee delivery of your product in the required conditions, on time. We provide a range of shipping solutions and have established strategic relationships with approved distribution partners and specialist airlines. We can also act as Importer of Record (IoR) as required.

### GMP floorspace

Flexibility, cost and time are key criteria in evaluating options in a “build or buy” decision for your technology. We offer dedicated, fully customisable, qualified GMP floorspace to suit your individual requirements allowing you to perform your own processes and enabling you to move rapidly and cost effectively through your drug development programme.

>90%
On Time, In Full (OTIF)

>25,000
shipments p.a.

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Find out more about our support solutions

# Almac Pharma Services - **Global reach**

Regulatory approval:

Brazil Canada Colombia E.U Ireland Israel Japan Mexico Russia S.Korea Turkey UK USA


## Facilities:



### Audubon, USA

- Primary Packaging
- Secondary Packaging
- Specialist ATMP solutions
- Complex kit assembly
- Product launch
- GMP footprint available



### Dundalk, EU

- QP certification & batch release
- Analytical development & QC
- Secondary packaging
- Specialist ATMP solutions
- Complex kit assembly
- Product launch
- GMP footprint available



### Craigavon, UK

- Non-GMP & GMP SOD development & clinical manufacture inc. HC
- Analytical Development & QC
- Early Phase Formulation Development
- Age-Appropriate Development
- Commercial manufacturing
- Primary Packaging
- Secondary Packaging
- QP certification & batch release
- Product launch
- GMP footprint available



### Charnwood, UK

- GMP Oral Dose development & clinical manufacture inc. HC
- Analytical development & QC
- Age-Appropriate product development
- Bioavailability enhancement
- Non-Sterile Liquid development & manufacture
- Small scale commercial manufacturing
- GMP footprint available

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Find out more about Almac Pharma Services

# Why choose Almac?

- **Highly experienced and dedicated teams:**
  Our teams bring a wealth of experience and dedication, ensuring expert solutions for every project.

- **Industry leading project management:**
  We excel in project management, setting high standards for efficiency and effectiveness.

- **Flexibility to meet your growing needs:**
  Our flexible approach allows us to adapt and meet your evolving requirements seamlessly.

- **Reputation for quality:**
  We are a quality-driven organisation and make the commitment to our clients, large and small, to deliver high-quality results every time.

- **Results driven:**
  Our focus is on achieving tangible, impactful results that drive the success of your product.

- **Collaborative partnership:**
  We believe in building strong, collaborative partnerships to achieve the mutual goal of drug development and commercial success.

- **Continual investment in our people, facilities, capabilities, and technology:**
  We continuously invest in our team, infrastructure, and technology to stay at the forefront of innovation and capability.


Scan the QR Code to learn more about Almac Pharma Services.

almacgroup.com

## Get in touch

Global HQ
+44 28 3836 3363

EU HQ
+353 42 932 0718

Audubon, PA, USA
+1 610 666 9500

Charnwood, UK
+44 15 0926 0763

pharmaservices@almacgroup.com